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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/092,546	06/05/1998	BEAT KINDLER	6348	6213

25763 7590 03/23/2004

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INTELLECTUAL PROPERTY DEPARTMENT  
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MINNEAPOLIS, MN 55402-1498

EXAMINER

DESANTO, MATTHEW F

ART UNIT PAPER NUMBER

3763

DATE MAILED: 03/23/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/092,546

Applicant(s)

KINDLER ET AL.

Examiner

Matthew F DeSanto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2004.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-9,15-18,20,21 and 26 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1,2,6-9,15-18,20,21 and 26 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 6-9, 15-18, 20-21, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee (USPN 3759425).

Lee discloses a device for metered administering fluid of a fluid comprising a container having a piston through an outlet, a catheter connected to the outlet to the container having a front end and will inherently contain an injection needle. He teaches a valve having an inlet and an outlet and injection needle that can be attached to the distal end, the valve having an inlet and outlet end wherein flow of fluid is permitted from the outlet to the injection needle when pressure is exerted on the inlet end of the valve exceeds a pressure on the inlet end caused by the pressure of the fluid drug. (Figures 1-8, and entire reference)

3. Claims 1, 2, 6-9, 15, 16, 17, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Caldwell et al. (USPN 4,93,009).

Caldwell et al. discloses a device for metered administering fluid of a fluid comprising a container having a piston through an outlet, a catheter connected to the outlet to the container having a front end and will inherently contain an injection needle. He teaches a valve having an inlet and an outlet and injection needle that can be

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attached to the distal end, the valve having an inlet and outlet end wherein flow of fluid is permitted from the outlet to the injection needle when pressure is exerted on the inlet end of the valve exceeds a pressure on the inlet end caused by the pressure of the fluid drug. (Figures 2, 2B, 4-6, and entire reference)

4. Claims 1, 2, 6-9, 15, 16, 17, 18, 20, 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Winnard (USPN 3,601,151).

Winnard discloses a device for metered administering fluid of a fluid comprising a container having a piston through an outlet, a catheter connected to the outlet to the container having a front end and will inherently contain an injection needle. He teaches a valve having an inlet and an outlet and injection needle that can be attached to the distal end, the valve having an inlet and outlet end wherein flow of fluid is permitted from the outlet to the injection needle when pressure is exerted on the inlet end of the valve exceeds a pressure on the inlet end caused by the pressure of the fluid drug. (Figures 1, 4, and entire reference)

5. Claims 1, 2, 6-9, 15 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Cardenas (USPN 5616133).

Cardenas discloses a device for metered administering fluid of a fluid comprising a container having a piston through an outlet, a catheter connected to the outlet to the container having a front end and will inherently contain an injection needle. He teaches a valve having an inlet and an outlet and injection needle that can be attached to the distal end, the valve having an inlet and outlet end wherein flow of fluid is permitted from the outlet to the injection needle when pressure is exerted on the inlet end of the valve

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exceeds a pressure on the inlet end caused by the pressure of the fluid drug. (Figures 1-4, 12, and entire reference)

***Response to Arguments***

6. Applicant's arguments filed 4/17/03 have been fully considered and are persuasive with regards to Abramson. The 102 rejection in view of Abramson has been withdrawn.

7. The examiner disagrees with the statement to Lee not teaching a driven member driving the piston towards the catheter wherein the piston is only held in the container or ampoule by frictional force. This is taught in Figures 1 and 2. There is no locking member or threads on the piston, therefore the plunger is holding the driving member in place by the frictional force caused by the plunger.

8. With regards to Cardenas, this prior art reference teaches the claimed structure and would be capable of performing the possible function of the claimed structure. Since this is an apparatus claim and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

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***Conclusion***

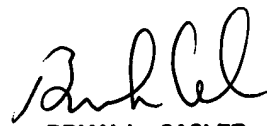
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Matthew DeSanto  
Art Unit 3763  
March 5, 2004



**BRIAN L. CASLER**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 3700**